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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 270,480	03 15 1999	MARKKU AHOTUPA	00013 7075	2552

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EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/270,480

Applicant(s)

Ahotupa

Examiner

Ralph Gitomer

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 6, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7-15 and 20-24 is/are allowed.
- 6) ☒ Claim(s) 1-6, 16-19, and 25 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e)

Attachments

- | | |
|--|---|
| 1. Notice of references cited: PTO 812 | 4. Interview summary: PTO 413-Paper No. 5 |
| 2. Notice of Draftsperson's Patent Drawing Review: PTO 946 | 5. Notice of Informal Patent Application: PTO 152 |
| 3. Information Disclosure Statement(s): PTO 1413-Paper No. 6 | 6. Other: |

The amendment received 12/6/2002 has been entered and claims 1-25 are currently pending in this application. The amended abstract and copy of the Declaration are acceptable.

5 In view of the amendments to the claims, the rejection of record under 35 USC 112, second paragraph, is hereby withdrawn.

In view of the arguments presented and amendments to the claims, the rejection of record of claims 7-15, 20-24 under 35 USC 103(a) is hereby withdrawn.

10 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

15 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be
20 negated by the manner in which the invention was made.

Claims 1-6, 16-19, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Wieland in view of Vasankari.

25 No single point of novelty is seen in the claims. And no background of the invention is provided to assist in

1. Separate LDL from plasma with a heparin solution to precipitate lipids.
2. Separate LDL from lipids with chloroform:methanol solution.
3. Determining baseline level of conjugate dienes in the lipid
5 fraction with cyclohexane.

Each of these steps is well known for its art recognized function. To combine each known step with the expected result would have been obvious. And to perform known steps with a kit is not novel. One would be motivated to incorporate the claimed
10 hardware and reagents into a kit with the expectation of commercial success because advantages include ease of automation, small volume of plasma samples, faster analysis time, increased sensitivity and the potential for an increased degree of standardization. Claim 25 is only a container of buffered
15 heparin where instructions are given no weight.

Wieland (J of Lipid Res) entitled ❖A Simple Method for Precipitation of Low Density Lipoproteins❖ teaches on page 904 column 2 first full paragraph, LDL's can be precipitated with
20 heparin where VLDL and HDL remain in solution. LDL lipids may then be determined by various techniques after selective precipitation.

The claims differ from Wieland in that they then determine LDL lipids by extracting with chloroform:methanol, then cyclohexane.

Vasankari (Clinica Chimica Acta) entitled Measurement of Serum Lipid Peroxidation During Exercise using Three Different Methods teaches on page 65, extracting lipids from serum samples with chloroform:methanol, then cyclohexane.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the LDL lipids determination as described by Wieland with the method of Vasankari because there are a number of known methods of extracting the lipid fraction and any of the known methods would have the expected result. To select the method of Vasankari would have been obvious because it would have the expected result.

Regarding claim 25 directed to a container containing heparin and instructions, no weight is given in a kit claim to any instructions which may accompany the reagents or apparatus of the kit. Containers of heparin are known.

Applicant's arguments filed 12/6/2002 have been fully considered but they are not persuasive.

Applicant argues that Wieland teaches precipitation of LDL.

fraction, only a lipid extraction. The references are not properly combinable.

It is the examiner's position that the present claims are now directed to a kit and the limitations of the claimed kit are taught by the cited references for the same function as claimed. Wieland would be first isolating LDL's and then LDL lipids. Wieland teaches precipitating LDL's with heparin and then LDL lipids may be determined, see page 904 column 2. Regarding Vasankari, what the lipids were extracted from is not critical to the invention but that the same solvents as presently claimed were employed to extract lipids from a sample containing lipids.

Applicant's failure to consider the references together is inappropriate in view of the fact that the rejection was made under 35 U.S.C. § 103, on the basis of what the combined teachings of the references would have suggested to one of ordinary skill in the relevant art, and not under 35 U.S.C. § 102, on the basis of anticipation by any of the individual references.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to

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www.uspto.gov and click on the button Patent Electronic Business
Center for more information.

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Ralph Gitomer
Primary Examiner
Group 1651